SYBRON DENTAL SPECIALTIES

K061042

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

JAN 19 2007

Sybron Dental Specialties, Inc.
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Colleen Boswell - Contact Person

Date Summary Prepared: April 2006

Device Name:

- Trade Name - *LingLock*
- Common Name - Lingual Orthodontic Retainer
- Classification Name - Retainer, Screw Expansion, Orthodontic, per 21 CFR § 872.5410

Devices for Which Substantial Equivalence is Claimed:

- Ormco Corporation, *Bondable Lingual Retainer*
- 3M Unitek, *Clarity Ceramic Brackets*

Device Description:

The device is an interlock retainer composed of polycrystalline alumina (aluminum oxide) that is bonded to the lingual surface of the lower anterior teeth and is intended to stabilize the lower dental arch following orthodontic treatment. *LingLock* is comprised of a set of ceramic attachments (male/female) bonded to the teeth across the contact points of the lower six anterior front teeth; the male component on one side and the female component on the other. When engaged, the ceramic attachments prevent the teeth from shifting out of position, yet have a slight gap which enables patients to floss their teeth interdentally in a regular manner.

The *LingLock* retainer has an application tool consisting of a ceramic attachment holder (polypropylene) and a guide strip (stainless steel) which ensures an exact positioning of the ceramic attachments both in relation to each other and the teeth to be retained. An orthodontic adhesive is placed on the bonding surface of the ceramic attachments and the guide strip is guided in between two neighbouring teeth. The ceramic attachment holder is brought in contact with the enamel at the lingual surface of the teeth and the orthodontic adhesive is light cured. After curing, the guide strip is removed by pulling it forward in a slight upward rotational movement. The ceramic attachment holder is then removed.

Intended Use of the Device:

The intended use of *LingLock* is to stabilize the lower dental arch following orthodontic treatment. The *LingLock* retainer enables patients to floss their teeth interdentally in a regular manner.

Substantial Equivalence:

LingLock is substantially equivalent to other legally marketed devices in the United States. *Linglock* functions in a manner similar to and is intended for the same use as the *Bondable Lingual Retainer* currently manufactured by Ormco Corporation and is composed of the same material and has the same bonding surface as the ceramic bracket manufactured by 3M Unitek.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Colleen Boswell
Vice President, Regulatory Affairs
Sybron Dental Specialist, Incorporated
100 Bayview Circle, Suite 6000
Newport Branch, California 92660-8915

JAN 19 2007

Re: K061042
Trade/Device Name: LingLock
Regulation Number: 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: II
Product Code: DYW
Dated: December 29, 2006
Received: January 4, 2007

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

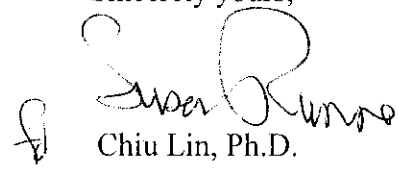
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061042

Device Name: *LingLock*

Indications For Use:

LingLock is an interlock retainer composed of polycrystalline alumina that is bonded to the lingual surface of the lower anterior teeth and is intended to stabilize the lower dental arch following orthodontic treatment. The *LingLock* retainer enables patients to floss their teeth interdentally in a regular manner.

Christina Chung
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K061042

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)